

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Application No.: 09/231,854
Filing Date: January 14, 1999
Applicants: Michael A. Martinelli et al.
Group Art Unit: 3737
Examiner: Ruth S. Smith
Title: METHOD AND SYSTEM FOR NAVIGATING A
CATHETER PROBE
Attorney Docket No.: 5074A-000032/REA

Mail Stop Amendment
Commissioner for Patents
P.O. Box 1450
Alexandria, Virginia 22313-1450

DECLARATION UNDER 37 C.F.R. §1.132

Sir:

1. I, David Simon, Ph.D., am Chief Technology Officer, Vice President Research & Development for Medtronic Navigation, Inc. I have been employed at Medtronic Navigation, Inc. for 10.5 years. I have worked in the field of imaging, such as patient imaging; surgical navigation; and associated programming and systems development for 17 years. I have received a doctorate degree from Carnegie Mellon University in Robotics with applications to Medicine, a master's degree from Carnegie Mellon University in Electrical and Computer Engineering, and a bachelor's degree from Princeton University in Electrical Engineering and Computer Science.

2. I have read and understand the disclosure of U.S. Patent No. 5,592,939 (herein the '939 patent). The '939 patent describes fully, clearly, and concisely a manner and process and also enables me to make and use a system and method of determining the location of at least one magnetically-sensitive, electrically conductive sensing coil affixed to a medical device partially inserted into a body cavity within a navigational domain including inducing within the at least one sensing coil, a set of induced signal values corresponding to a set of location parameters. The method is recited in Claims 28 and 29 added in the re-issue application 09/231,854 filed on January 14, 1999, which is a re-issue of U.S. Patent No. 5,592,939.

3. The '939 patent describes a separation of variables technique that can be used uniquely solve five unknowns. See, the '939 patent, col. 6, lines 38-49. The five unknowns are two variables that describe orientation, theta and phi, and three positional coordinates, x-y-z position coordinates. See, the '939 patent, col. 7, lines 26-31.

4. The '939 patent clearly describes equations and algorithms for determining the orientation and position of a sensing coil using the separation of variables technique. See, the '939 patent, col. 7, ln. 41- col. 12, ln. 36. The '939 patent discloses that a sensing coil can sense the fields produced relative to it and a determination of an orientation and position of the sensing coil can be based upon the sensed fields. See, *Id.*

5. The '939 patent describes a system can include multiple sensing coils. For example, a second sensing coil can be used for stabilization purposes. See, the '939 patent, col. 15, lines 2-3. Further, the '939 patent describes, in a multi-catheter

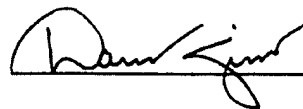
application, that additional sensing coils can be attached to the distal end of each additional catheter. See, the '939 patent, col. 15, lines 11-14.

6. Therefore, the system and method described in '939 patent enables me to determine the orientation and position of at least one and more than one sensing coil affixed to a single instrument, catheter, etc. As noted above, the '939 patent clearly describes both (1) a method and system for determining the location of one sensing coil and (2) that more than one sensing coil can be located. In a system or method with more than one sensing coil, the '939 patent does enable me to make and use a system to determine a location of the multiple sensing coils. Thus, using the disclosure of the '939 patent, I am enabled to make and use a system and method to determine the location of at least one magnetically-sensitive, electrically conductive sensing coil affixed to a medical device.

7. I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under 18 U.S.C. § 1001 and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

1.28.08

Date



David Simon, Ph.D.